DETAILED ACTION

1. This action is in response to the papers filed 4/13/2009.

2. Currently Claims 1-15 and 20-21 are pending.

3. Claims 10 and 12-15 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/09/2008.

4. Claims 16-19 have been cancelled. It is noted that the claims are listed as "withdrawn" on the amendments to the claims, however, in the response to amendments the claims are indicated to be cancelled (p. 8 5th paragraph). A phone call to Susan Rancourt on 3/24/2010 confirmed that these claims are to be cancelled. It is noted that the descriptor for claims 16-19 should be listed as "cancelled" in all future claim amendments.

5. The following rejections are necessitated by amendment. Response to arguments follows.

6. This action for claims 1-9, 11 and 20-21 is FINAL.

Withdrawn Objections and Rejections

7. The objection to the claims made in section 5 of the previous office action is moot based upon amendments to the claims .

8. The rejection of the claims 1, 8-9, 11, and 16-19 made in section 6 are moot based upon amendments to the claims or cancellation of the claims.

9. The rejection of the claims under 35 USC 112/Written Description presented on p. 19-23 of the previous office action is moot based upon amendments to the claims.

10. The rejection of the claims under 35 USC 101 made on p. 24 of the previous office action is moot based upon amendments to the claims.

11. The rejection of the claims under 35 USC 102(b) made on p. 25 of the previous office action is moot based upon the cancellation of the claims.

Claim Rejections - 35 USC § 112/Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 2-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-7 are indefinite over the phrase “the presence or absence of the at least one C allele" in lines 6-7 of claim 2. It is unclear if the "C allele" is the same as in claim 1 or if it encompasses another position in IGF2 not represented by position 150 of SEQ ID No. 1.

Response to Arguments

The reply asserts that the phrase as been amended to read "the at least one C allele" to reflect the language of claim 1 (p. 7 4th paragraph).

This has been fully reviewed but have not been found persuasive.

Claim 1 is drawn to one specific C allele at one position. However claim 2 refers to "at least one" C allele. As such it is not clear if the claim is referring to the one allele of claim 1, a combination of the allele in claim 1 and another undefined alleles, or undefined alleles. As such the claims are indefinite.

Claim Rejections - 35 USC § 112/Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

A method for identifying increased rib eye area (REA) in bovine cattle, the method comprising isolating a genomic sample from bovine cattle, detecting a "C" or a "T" at position 150 of SEQ ID No. 1, identifying the bovine cattle with two copies of a "C" allele at position 150 of SEQ ID No. 1 as having increased REA compared to both bovine cattle with two copies of the "T" allele at position 150 of SEQ ID NO. 1 and bovine cattle with one copy of the "C" allele at position 150 of SEQ ID No. 1 and one copy of the "T" allele at position 150 of SEQ ID NO. 1.

, does not reasonably provide enablement for identifying the phenotype of increased rib eye by detecting only the presence of a single C allele at position 150 of

SEQ ID No. 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

Breadth of the claims

Claims 1-9 encompass identification of increased rib eye area (REA) by detecting of the C allele at position 150 of SEQ ID No.1. This would therefore encompass association of both CC genotype to increased REA and CT genotype with increased REA. As discussed below, the specification only provides a positive correlation to the CC genotype and increased REA.

Nature of the Invention

The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Teachings in the Specification and Working Examples

The specification discloses that insulin-like growth factor 2 (IGF2) is a 67 amino acid peptide hormone having multiple phenotypic effects on cellular growth and metabolism (p. 3 lines 13-15). The specification discloses that the IGF2 comprises 10 exons in pig and 9 exons in sheep (p. 3 lines 15-19). The specification discloses that there is no equivalent exon 2 in sheep (p. 3 lines 15-19). The specification asserts that the SNP of interest is in exon 2 of IGF2 and comprises a C to T transition at position 150 of SEQ ID No. 1 (p. 9 lines 1-5).

The instant specification discloses that 17 full-sib families of Canadian Beef cattle were used (p. 31 lines 5-9). The instant specification discloses a method of detection the SNP at position 150 of SEQ ID No. 1 as a C or a T to determine if the particular bovine is homozygous or heterozygous for the particular allele (p. 31- 33).

The specification asserts that in animals (e.g. Canadian beef cattle) the C/T allelic genotype had significantly smaller REA size compared to homozygous C/C offspring (p= 0.0004) (p. 34 lines 10-15). The specification asserts that in the 125 cattle studies REA was significantly correlated with the number of C alleles present (p= 0.0001) (p. 34 liens 10-17). The specification asserts that in 167 bulls REA was still positively correlated with the number of C alleles (p= 0.459) and that cattle with C/C genotype had a significantly larger REA than the C/T or T/T genotype (p=0.0413) (p. 34 lines 20-23 and p. 35 lines 1-5). Therefore the instant specification provides a statistically significant correlation or increased REA wherein a bovine cattle has a

specific genotype.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied prior to being able to practice the claimed invention as broadly as written. The skilled artisan would have to determine an association of increased REA with the detection of CT genotype whereas the instant specification only provides a significant correlation of the CC genotype in cattle. Therefore the claims as broadly encompassed would require significant inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

Case law has established that '(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that '(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art. Furthermore, the Court in *Genetech Inc. v*

Novo Nordisk 42 USPQ2d 1001 held that '(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement".

In view of this unpredictability, the specification has not established that the presently claimed method can be used to determine increased REA by detection of the CT genotype.

Response to Arguments

The reply traverses the rejection. A summary of the arguments presented in the reply is provided below with response to arguments following.

The reply asserts that the claims have been amended to indicated that the phenotype detected is increased REA and that the polymorphisms is a C/T polymorphism (p. 8 last paragraph).

This have been fully reviewed but have not been found persuasive.

As noted above the instant specification only provides a predictable association of detecting the CC genotype with increased REA, however, the claims are drawn to associating increased REA with both CC and CT cattle. Further it is noted that the claims are unpredictable because it is unclear what the phenotype would be if a CT is determined. It is not clear in the instance of a CT if the phenotype would be increased REA or decreased REA because as the claims are amended the claims only require that the C is increased compared to the T. In the case were there is a CT, the genotype

has both a C and a T and therefore it is unclear how the cattle would have both an increased and a decreased REA.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

14. Claims 11, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Byatt et al. (US Patent Application September 26, 2002).

With regard to Claim 11, Byatt et al. teaches genome mapping of cattle (abstract). Byatt et al. teaches sequences can be compared to other DNA sequences to determine homology and that similarities between tow sequences can be determine (p. 2 paragraph 14 and 15). Byatt et al. teaches a method of sequencing (e.g. genotyping) SEQ ID No. 3018 in cattle (p. 4 paragraph 24 and sequence descriptor). SEQ ID No. 3018 is identical to SEQ ID No. 1 and therefore Byatt et al. would detect whether the animal has a C residue at position 150 (see alignment below). Byatt et al. teaches a method of determining the presence or absence of a mutation encompassed by in the sequence of SEQ ID NO. 3018 (p. 5 paragraph 33). Byatt et al. teaches determining in a bovine if there is complete hybridization to SEQ ID No. 3018 (p. 5 paragraph 33). As such Byatt et al. teaches determining whether the animal has a C allele at position 150

of SEQ ID No. 1 (e.g. the wild type). As such Byatt et al. is sorting the bovine between animals that have a mutation and animals that have the wild type.

With regard to Claim 20, Byatt et al. teaches genome mapping of cattle (abstract). Byatt et al. teaches sequences can be compared to other DNA sequences to determine homology and that similarities between tow sequences can be determine (p. 2 paragraph 14 and 15). Byatt et al. teaches a method of sequencing (e.g. genotyping) SEQ ID No. 3018 in cattle (p. 4 paragraph 24 and sequence descriptor). SEQ ID No. 3018 is identical to SEQ ID No. 1 and therefore Byatt et al. would detect whether the animal has a C residue at position 150 (see alignment below).

With regard to Claim 21, Byatt et al. teaches isolating this genomic DNA sample using primer pairs (p. 8 paragraph 72).

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Query Match             99.1%;  Score 214.6;  DB 3;  Length 438;
  Best Local Similarity   99.1%;  Pred. No. 1.3e-56;
  Matches  214;  Conservative    1;  Mismatches    1;  Indels    0;  Gaps
0;

Qy          1 CCTCAGCCTCATCCCCTCCTTTGCCTCCCAGTCAAGCCTGCTGGGGGGTCTGAGCACCAC 60
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Qy         61 AGCCAGAGCACCCCCGCCTTGGCAGCGACTGCTACTATTGGCCCAGCCAGCGGATCATCC
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Qy        121 ACCTGGCAGTCGAGAGCCTGGGGCACCAGYGACGTCCAGGTCCTCTTTACCCACCGCCCA
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Qy        181 GGGGAGCTTCAGAGACAACACAGCAAATAGAGCACA 216
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Db        240 GGGGAGCTTCAGAGACAACACAGCANATAGAGCACA 275
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Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE SALMON whose telephone number is (571)272-3316. The examiner can normally be reached on Monday - Friday 9AM-530PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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